

## Protecting and Improving the Health of Iowans

Kim Reynolds, Governor

Adam Gregg, Lt. Governor

Kelly Garcia, Interim Director

# Healthcare Provider COVID-19 Vaccine Frequently Asked Questions Updated November 20, 2020

Changes from the previous version are highlighted in yellow.

#### **COVID-19 Vaccine Program Provider Agreement**

- 1. Does each individual healthcare provider need to complete the REDCap survey/COVID-19 Vaccine Program Provider Agreement, or can the healthcare organization complete the REDCap survey?
  - The REDCap survey/COVID-19 Vaccination Program Provider Agreement should be completed by the healthcare organization. Individual healthcare providers DO NOT need to complete the REDCap survey. Providers practicing in the healthcare organization should be listed as prescribers within the REDCap survey/COVID-19 Vaccination Program Provider Agreement for each organization.
- 2. Is there a deadline to enroll in IRIS and complete the REDCap/COVID-19 Vaccine Program Provider Agreement?
  - No, IDPH will leave the REDCap survey open throughout the COVID-19 vaccination campaign. Healthcare organizations can complete the REDCap survey and enroll in IRIS at any time. IDPH encourages healthcare organizations to enroll as soon as possible.
- 3. In order to receive COVID-19 vaccine, do healthcare organizations need to become Vaccines for Children Program providers in addition to completing the REDCap/COVID-19 Vaccine Program Provider Agreement to become a COVID-19 vaccine provider?
  - No, healthcare organizations do NOT need to enroll in the Vaccines for Children Program to become COVID-19 vaccine providers. However, the healthcare organization is required to enroll in IRIS, see question 4.

4. Will healthcare organizations wanting to provide COVID-19 vaccines need to sign an agreement to receive the vaccine?

Yes. Healthcare organizations must enroll in IRIS and agree to terms in the federal COVID- 19 Vaccination Provider Agreement. Signing a COVID-19 Vaccination Provider Agreement does not ensure the healthcare organization will receive COVID-19 vaccine and ancillary supplies. The CDC COVID-19 Vaccination Provider Agreement will be included as part of a REDCap survey.

5. Do healthcare organizations already enrolled in IRIS still need to complete the COVID-19 Vaccination Program Provider Agreement?

Yes. All healthcare organizations planning to receive and administer COVID-19 vaccines must complete a COVID-19 Vaccination Program Provider Agreement.

6. Who should healthcare organizations enter for the Chief Medical Officer in the RedCap survey if the organization does not have a CMO?

Healthcare organizations without a Chief Medical Officer or similarly titled position should use the name of the physician who signs the organizations' standing orders. Questions can be directed to the Immunization Program at 1-800-831-6293, Option 1 or COVID19Vaccine@idph.iowa.gov.

7. The COVID-19 Vaccination Program Provider Agreement/REDCap survey asks for the number of patients or clients a clinic serves. How do we ensure the same patients are not also captured by another clinic?

Patient population should include individuals the healthcare organization normally serves. It is understood this information is an estimate and will be used for planning purposes.

8. Our hospital has several outlying clinics. Does each clinic need to enroll to become a COVID-19 vaccine provider, or can they operate under the hospital's enrollment and provider agreement?

The hospital and each healthcare organization site would need to complete a COVID-19 Vaccination Program Provider Agreement. This allows for the COVID-19 vaccine to be shipped directly to each healthcare organization site and COVID-19 vaccine doses administered to be documented appropriately for each organization in IRIS.

9. Can healthcare organizations already enrolled in IRIS add additional users for the organization?

Yes. An admin user in each healthcare organization can add additional users. Contact the IRIS Help Desk at 800-374-3958 for additional assistance.

10. Does the provider agreement provide any liability protection for the provider? The CDC COVID-19 Vaccine Provider Agreement specifies the requirements to receive, store and administer COVID-19 vaccines.

The administration of COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program. The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the CICP to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the covered countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of covered countermeasures identified in a PREP Act declaration. The <a href="PREP Act declaration">PREP Act declaration</a> for medical countermeasures against COVID-19 states that the covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP and filing a claim are available at the toll-free number 1–855–266–2427 or <a href="http://www.hrsa.gov/cicp/">http://www.hrsa.gov/cicp/</a>.

#### COVID-19 Vaccine / Vaccine Administration

1. Will vaccine recipients be required to show their COVID-19 vaccination record card in order to get the second dose?

No. However, all vaccine recipients should be encouraged to keep their card and show it at their follow-up vaccination appointment. Retaining the COVID-19 vaccination record card is important to ensure the second dose of vaccine is the same brand/manufacturer as the first dose received. The purpose of the vaccination record card is to provide documentation for the patient to take with them following vaccination. IRIS will serve as the permanent medical record and can be used to generate patient specific immunization reports.

2. Will more than one dose of COVID-19 vaccine be needed?

It is anticipated the first available COVID-19 vaccines will require two doses separated by intervals of >21 or >28 days depending on the vaccine product.

The different vaccine products will NOT be interchangeable. The series of two doses must be completed with the same vaccine product. Second dose reminders for patients will be necessary.

3. For COVID-19 vaccines requiring a 2nd dose, should healthcare providers reserve the second dose? No. Vaccines should not be held back to ensure persons receive their second dose. It is anticipated additional allocations will be made available to accommodate the second dose.

#### 4. How will the COVID-19 vaccines be administered?

At this time, the initial doses of COVID-19 vaccines are expected to be administered by intramuscular (IM) injection. Depending on the brand of vaccine, reconstitution of the vaccine may be required. More information will be shared as it becomes available.

#### 5. Is the COVID-19 vaccine a live vaccine?

There are currently multiple vaccine candidates in various stages of clinical trials. The first two COVID-19 vaccines anticipated to be available are not live vaccines. More information will be shared as it becomes available.

6. Who will be eligible to receive the first available COVID-19 vaccines?

Limited COVID-19 vaccines will be available initially. The vaccine supply is expected to increase substantially in 2021. Groups prioritized for initial COVID-19 vaccination have not yet been confirmed but are expected to be critical infrastructure, healthcare workers and high risk individuals.

### 7. Is there guidance for safely administering vaccines during the COVID-19 pandemic?

CDC has released Interim Guidance for Routine and Influenza Immunization Services During the COVID-19 Pandemic. This guidance is intended to help immunization providers in a variety of clinical and alternative settings with the safe administration of vaccines during the COVID-19 pandemic. This guidance will be continually reassessed and updated based on the evolving epidemiology of COVID-19 in the United States.

Interim guidance: Immunization services during the COVID-19 pandemic: Vaccination and COVID-19Vaccination Guidance During a Pandemic

Protective Measures for Vaccinating During Pandemic

8. Are there specific infection control procedures to follow when administering vaccines during a pandemic?

It is important to apply infection prevention strategies to all patient encounters including physical distancing, respiratory and hand hygiene, surface decontamination, and source control. The CDC has developed <u>General Practices for Safe Delivery of Vaccination Services</u> and the Immunization Action Coalition has developed <u>Protective Measures for Vaccinating During Pandemic</u>.

9. Is there guidance for administering vaccines in a setting other than a doctor's office (e.g., pharmacies; temporary, off-site, or satellite clinics; and large-scale influenza clinics)?

Yes. Guidance has been developed for giving vaccines at <u>pharmacies</u>, <u>temporary</u>, <u>off-site</u>, <u>or satellite clinics</u>, and <u>large-scale influenza clinics</u>. Other approaches to vaccination during the COVID-19 pandemic may include drive-through immunization services at fixed sites, curbside clinics, mobile outreach units, and home visits. Please collaborate these plans with Local Public Health Agencies.

The general principles outlined for <u>healthcare facilities</u> should also be applied to alternative vaccination sites, with additional precautions for physical distancing that are particularly relevant for large-scale clinics, such as:

- Providing specific appointment times or other strategies to manage patient flow and avoid crowding.
- Ensuring sufficient staff and resources to help move patients through the clinic as quickly as possible.
- Limiting the overall number of patients at any given time, particularly for populations at higher risk for severe illness from COVID-19.
- Setting up a one-way flow through the site and using signs, ropes, or other measures to direct patient traffic and ensure physical distancing between patients.
- Arranging a separate vaccination area or separate hours for persons at increased risk for severe illness from COVID-19, such as older adults and persons with underlying medical conditions, when feasible.
- Selecting a space large enough to ensure a minimum distance of 6 feet between
  patients in line or in waiting areas for vaccination, between vaccination stations,
  and in post vaccination monitoring areas (the Advisory Committee on
  Immunization Practices recommends providers consider observing patients for
  15 minutes after vaccination to decrease the risk for injury should they faint).
  Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or
  Off-Site Locations Considerations for Planning Curbside/Drive Through
  Vaccination Clinics

#### 10. Will ancillary supplies be included with COVID-19 vaccine?

Yes. COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to lowa healthcare providers who have completed a COVID-19 Vaccine Provider Agreement. Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders.

Each kit will contain supplies to administer 100 doses of vaccine, including:

- Needles, 105 per kit (various sizes for the population served)
- Syringes, 105 per kit
- Alcohol prep pads, 210 per kit
- 4 surgical masks and 2 face shields for vaccinators, per kit
- COVID-19 vaccination record cards for vaccine recipients,100 per kit

Bandages, gloves, and sharps containers will not be included. Mixing kits to reconstitute a vaccine product include needles, syringes, and alcohol prep pads for use with vaccines requiring an adjuvant or diluent mixed at the administration site.

#### 11. Will COVID-19 vaccine be reported in IRIS?

Healthcare organizations who receive and administer COVID-19 vaccines will be required to enter doses of vaccine administered in IRIS within 24 hours after administration.

#### 12. Will there be a required observation period after vaccination?

ACIP currently recommends providers should consider observing patients for 15 minutes after receipt of a vaccine.

### 13. We have already heard concerns from clients and patients about the safety of a new vaccine. How do we address this?

This is a very important point. The CDC and IDPH will be addressing vaccine confidence throughout the COVID-19 vaccination campaign. CDC is in the process of developing materials to address concerns about COVID-19 vaccines. Additional information will be shared when materials are available.

14. Can vaccine information be provided in multiple languages so we can help build trust for the vaccine among the diverse populations in our communities?
CDC and other public health partners are working on a communication campaign which will include multiple languages and formats. Information will be shared as it becomes available.

#### 15. When will the first doses of COVID-19 vaccine be available?

It is anticipated very small amounts of vaccine will be made available late fall 2020 with supplies increasing in early 2021.

### 16. Are there any contraindications with providing COVID-19 vaccine while someone is being treated with antivirals for influenza?

IDPH does not have any information on contraindications at this time. Information will be shared as COVID-19 vaccines complete clinical trials and are either approved by the FDA or are distributed under an Emergency Use Authorization (EUA).

#### 17. Will the vaccine be mandatory for essential healthcare workers?

IDPH does not anticipate a state mandate to receive COVID-19 vaccine. Similar to influenza requirements, health systems and clinics may choose to set policies requiring COVID-19 vaccine for organization staff.

### 18. If someone has already had COVID-19 and recovered, do they still need to be vaccinated with a COVID-19 vaccine when it is available?

Currently, there is not enough information available to determine if or for how long after infection someone is protected from getting COVID-19 again (natural immunity). Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Additional information will be made available once the Advisory Committee on Immunization Practices makes recommendations to CDC on how to use COVID-19 vaccines.

19. Can people stop wearing a mask after being vaccinated with COVID-19 vaccine? Currently, there is not enough information available to determine if or when CDC will stop recommending people wear masks to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

### 20. Does immunity after getting COVID-19 last longer than protection from COVID-19 vaccines?

The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Since this virus is new, it is unknown how long natural immunity might last. Some early evidence suggests natural immunity may not last very long.

It is also currently unknown how long immunity from the vaccine will last. Additional information about the duration of immunity will be forthcoming.

### 21. What percentage of the population needs to be vaccinated to have herd immunity to COVID-19?

At this time, experts do not know what percentage of people need to be vaccinated to achieve herd immunity to COVID-19. Herd immunity is a term used to describe when enough people have protection from either previous infection or vaccination to prevent the spread of the virus or bacteria in the community. As a result, everyone within the community is protected even if some people don't have any protection themselves. The percentage of people who need to have protection in order to achieve herd immunity varies by disease.

#### 22. Will COVID-19 vaccine cause me to test positive on a COVID-19 viral test?

Vaccines currently in clinical trials in the United States will not cause you to test positive on viral tests, which are used to see if you have a current infection.

If your body develops an immune response, which is the goal of vaccination, there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and may have some level of protection against the virus. Experts are currently working to assess how COVID-19 vaccination may affect antibody testing results.

#### **COVID-19 Allocation and Distribution**

1. How will doses of vaccine be allocated and distributed to healthcare organizations, how will the organization be notified of a COVID-19 vaccine order?

Counties (LPHAs) receive allocation of COVID-19 vaccine from IDPH. LPHAs are the only entities in each county able to allocate COVID-19 vaccine for healthcare organizations. LPHAs may allocate COVID-19 vaccine at their discretion consistent with the county's pandemic vaccine plan. Healthcare organizations will not order COVID-19 vaccines directly from the state or county. Healthcare organizations will receive an allocation from the LPHA based on local strategies for distribution of vaccine to priority populations. The allocation of vaccines to healthcare organizations by the LPHA will create a vaccine order in IRIS and generate an email notification to the organization. *COVID-19 vaccine orders will be distributed directly to the healthcare organizations from a CDC contracted distributor.* 

2. A healthcare organization has an office in one county, but the main office is either out of county or out of state. Who does the clinic work with to receive COVID-19 vaccine?

LPHAs/counties in Iowa will allocate doses of vaccine to healthcare organizations only within their respective counties. Each healthcare organization location will be required to sign a COVID-19 Vaccination Provider Agreement and must work with the corresponding county to receive the vaccine.

3. Can vaccine be redistributed among providers within the same health system? As much as possible, vaccine will be shipped to the healthcare organization location where it will be administered to limit the possibility of storage and handling issues. However, due to minimum order quantities, transferring the vaccine will be an acceptable practice. COVID-19 vaccines may only be redistributed between IDPH approved COVID-19 providers. In addition, during the initial vaccination phase when COVID-19 vaccine supply is limited, redistribution of vaccine will only be permitted between healthcare organizations within the same county.

IDPH will be providing guidance about the process to transfer COVID-19 vaccine, approval process and the *requirement* to transfer vaccine doses in IRIS.

4. Can a healthcare organization choose to order/stock certain COVID-19 vaccines?

No. Allocations will be based upon available COVID-19 vaccines. LPHAs will work with healthcare organizations for the allocation and distribution of COVID-19 vaccines.

#### **COVID-19 Storage and Handling**

1. What are the storage and handling requirements for the COVID-19 vaccines?

The anticipated first available COVID-19 vaccines have varying storage and handling requirements, ranging from refrigerated (2-8° C) to frozen (-20° C) to ultra-frozen (-60° to -80° C). The manufacturers are conducting ongoing vaccine stability testing. Additional guidance will be provided as it is received.

An addendum to the CDC <u>Vaccine Storage and Handling Toolkit</u> specifically addressing COVID-19 vaccines is currently being developed in addition to other training materials.

2. Is it known how long it will take to thaw ultra-frozen stored COVID-19 vaccines from frozen to refrigerated?

This information has not been released from the vaccine manufacturer. Information will be shared as soon as it becomes available.

3. The Planning Assumptions refer to the ultra-frozen vaccine shipping container needing to be "recharged". Please clarify what this means.

The ultra-frozen vaccine will arrive in a shipping container able to maintain the -70°C ± 10°C storage requirement for 5 days. If the healthcare organization does not have ultra-frozen storage capacity, the shipping container will need to be replenished (recharged) with dry ice within 24 hours of receiving the shipment and again every 5 days if agencies plan to continue to store the ultra-frozen vaccine beyond the specified timeframe.

#### **COVID-19 Vaccine Administration Reimbursement**

- 1. Will healthcare organizations be able to charge for the COVID-19 vaccine? No. Healthcare organizations cannot charge for COVID-19 vaccines provided by the federal government. It is unknown at this time if an administration fee will be able to be charged. IDPH will share more information about reimbursement claims for administration fees as it becomes available from insurers and federal and state partners.
- 2. Can a client be turned away if they owe a previous balance to the provider?

  COVID-19 vaccine is being provided at no cost to participating vaccine providers and should be provided regardless of the individual's ability to pay or previous balance owed.
- 3. Can providers bill for an office visit when administering COVID-19 vaccine? Yes, providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient's plan. More information will be provided in the future regarding office visit fees and vaccine administration fees.
- 4. Will providers be able to charge a COVID-19 vaccine administration fee? Yes, vaccine providers will be able to charge an administration fee. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient's ability to pay COVID-19 vaccine administration fees or insurance coverage status, as stated in the CDC COVID-19 Vaccination Program Provider Agreement. Vaccine providers may seek appropriate reimbursement from a program or plan that covers COVID-19 vaccine administration fees for the vaccine recipient.

#### Influenza and COVID-19 Vaccines

#### 1. What is the difference between influenza (Flu) and COVID-19?

Influenza (Flu) and COVID-19 are both contagious respiratory illnesses, but are caused by different viruses. COVID-19 is caused by infection with a new coronavirus (called SARS-CoV-2) and flu is caused by infection with <u>influenza viruses</u>. Some of the symptoms of flu and COVID-19 are similar and it may be hard to tell the difference based on symptoms alone. Testing may be needed to help confirm a diagnosis. Flu and COVID-19 share many characteristics, but there are some key differences between the two. <u>This table</u> compares COVID-19 and flu, given the best available information to date.

#### 2. Will there be flu along with COVID-19 in the fall and winter?

CDC believes it is likely flu viruses and the virus causing COVID-19 will both be circulating this fall and winter. Getting a flu vaccine will be more important than ever. The CDC recommends all people 6 months and older receive the flu vaccine each year.

#### 3. Will receiving a flu vaccine protect against COVID-19?

Getting a flu vaccine will not protect against COVID-19, however flu vaccination has many other important <u>benefits</u>. Flu vaccines have been shown to reduce the risk of flu illness, hospitalization and death. Getting a flu vaccine this fall will be more important than ever, not only to reduce the risk from flu but also to help conserve potentially scarce healthcare resources.

### 4. What is the recommendation for receiving influenza vaccine this fall/winter with the current COVID-19 pandemic?

It is likely influenza viruses and the virus causing COVID-19 will both be circulating. The CDC recommends everyone > 6 months receive influenza vaccine yearly. During the COVID-19 pandemic, reducing the overall burden of respiratory illnesses is especially important to protect vulnerable populations at risk for severe illness, the healthcare system, and other critical infrastructure. Healthcare providers should use every opportunity to administer influenza vaccines to all eligible persons.

Additionally, a prior infection with suspected or confirmed COVID-19 or flu does not protect someone from future flu infections. The best way to prevent seasonal flu is to get vaccinated every year.

### 5. Can other vaccines, including influenza vaccines, be administered at the same time as the COVID-19 vaccines?

Once COVID-19 vaccines are authorized or approved by the FDA, the Advisory Committee on Immunization Practice will make recommendations for the administration of COVID-19 vaccine with other vaccines.

### 6. Should influenza vaccines be given to someone in an outpatient setting with suspected or confirmed COVID-19?

No. CDC recently provided <u>Interim Guidance for Immunization Services During the COVID-19 Pandemic</u>. Updates made related to vaccinating persons with suspected or confirmed COVID-19 or in quarantine due to COVID-19 exposure. The section, "Deferring Routine Vaccination Visits for Persons with Suspected or Confirmed COVID-19 Who are In Isolation or Persons with A Known COVID-19 Exposure Who Are in Quarantine," recommends postponing all vaccination visits for the following individuals:

- Asymptomatic and pre-symptomatic persons who have tested positive: 10 days from a positive test result
- Symptomatic persons: Met criteria to discontinue isolation; 10 days after symptom onset and 24 hours with no fever without the use of fever-reducing medications, and COVID-19 symptoms improving; and no longer moderately to severely ill
- Persons exposed to a person with COVID-19: After 14-day quarantine period has ended

When scheduling or confirming appointments for vaccination, patients should be instructed to notify the provider's office or clinic in advance if they currently have or developed any symptoms of COVID-19.

### 7. Should influenza vaccines be administered to someone with COVID-19 who is currently hospitalized or in another inpatient healthcare facility?

The CDC has provided specific guidance on consideration for influenza vaccination of persons in various healthcare facilities and congregate healthcare settings during the COVID-19 pandemic: <a href="Interim Guidance">Interim Guidance</a> for Routine and Influenza Immunization

Services During the COVID-19 Pandemic. Additional guidance is also available for persons in shelters or who are receiving homeless services and for persons in correctional or detention facilities.

Excerpt from <u>Prevention and Control of Seasonal Influenza with Vaccines:</u>

<u>Recommendations of the Advisory Committee on Immunization Practices-United</u>

<u>States</u>, 2020-21 Influenza Season:

Influenza Vaccination of Persons with SARS-CoV-2 Infection (COVID-19)

"Because SARS-CoV-2 is a novel coronavirus, clinical experience with influenza vaccination of persons with COVID-19 is limited. For those who have acute illness with suspected or laboratory-confirmed COVID-19, clinicians can consider delaying influenza vaccination until the patients are no longer acutely ill. If influenza vaccination is delayed, patients should be reminded to return for influenza vaccination once they have recovered from their acute illness."

Additionally, <u>General Best Practice Guidelines for Immunization</u>: Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP) states:

"The presence of a moderate or severe acute illness with or without a fever is a precaution to administration of all vaccines. The decision to administer or delay vaccination because of a current or recent acute illness depends on the severity of symptoms and etiology of the condition. The safety and efficacy of vaccinating persons who have mild illnesses have been documented. Vaccination should be deferred for persons with a moderate or severe acute illness. This precaution avoids causing diagnostic confusion between manifestations of the underlying illness and possible adverse effects of vaccination or superimposing adverse effects of the vaccine on the underlying illness. After they are screened for contraindications, persons with moderate or severe acute illness should be vaccinated as soon as the acute illness has improved."

Vaccination may be deferred if a precaution is present, although a vaccination might be indicated in the presence of a precaution if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. In deciding whether to vaccinate a patient with moderate or severe illness, the clinician needs to determine if deferring vaccination will increase the patient's risk of vaccine-preventable diseases, as is the case if the patient is unlikely to return for vaccination or to seek vaccination elsewhere.

#### **Pharmacy**

#### 1. Will pharmacies be allowed to administer COVID-19 vaccine?

Yes. Pharmacies will be allowed to receive and administer COVID-19 vaccine. Local Public Health Agencies may allocate doses of COVID-19 vaccine to healthcare organizations in the county who have signed a COVID-19 Vaccination Program Provider Agreement.